

By-law of Institutional Review Board (IRB) For BioChain Institute Inc.

Definition

An **institutional review board** (IRB), also known as an **independent ethics committee** (IEC) or **ethical review board** (ERB) is a [committee](#) that has been formally designated to approve, monitor, and review [biomedical](#) and [behavioral research](#) involving [humans](#) with the alleged aim to protect the rights and welfare of the [research subjects](#). In the [United States](#), [Food and Drug Administration](#) (FDA) and [HHS](#), specifically [OHRP](#), regulations have empowered IRBs to approve, require modifications in (to secure approval), or disapprove research. An IRB performs critical oversight functions for research conducted on human subjects that are *scientific, ethical, and regulatory*.

"IRB" is a generic term used by the FDA and HHS. Each [institution](#) that establishes an IRB may use whatever name it chooses. Regardless of the name chosen, the IRB is subject to the FDA's IRB regulations when studies of FDA-regulated products are reviewed and approved.

Originally, IRBs were committees at [academic institutions](#) and [medical facilities](#) to monitor research studies involving human participants, primarily to minimize or avoid [ethical](#) problems. Today many IRB reviews are done by **for-profit** organizations. These are known as *independent* or *commercial* IRBs. The responsibilities of these IRBs are identical to those based at academic or medical institutions, and they are governed by the same federal regulations.

US Law Requirement

In the [United States](#), IRBs are governed by Title 45 CFR (Code of Federal Regulations) Part 46.^[1] This [Research Act of 1974](#), which defines IRBs and requires them for all research that receives funding, directly or indirectly, from what was the [Department of Health, Education, and Welfare](#) at the time, and is now the [Department of Health and Human Services](#) (HHS). IRBs are themselves regulated by the [Office for Human Research Protections](#) ([OHRP](#)) within HHS. IRBs were developed in direct response to research abuses earlier in the twentieth century. Title 21 part 56 has additional requirements for IRBs that oversee clinical trials of drugs involved in [New drug applications](#).

Since the Common Rule regulations were written with biomedical and laboratory science methods in mind, the fit is problematic between IRB review and social science methodologies, especially [ethnography](#). Federal agencies supporting social science have

attempted to provide guidance in this area, especially the National Science Foundation in its [Frequently Asked Questions](#) (FAQ). In general, the FAQ assures IRBs that the regulations have some flexibility and rely on the common sense of the IRB to focus on limiting harm, maximizing informed consent, and limiting pointless bureaucratic limitations of valid research.

Mission

The purpose of an IRB [review](#) is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. To accomplish this purpose, IRBs review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and [welfare](#) of human subjects of research. The chief objectives of every IRB protocol review are to assess the scientific merit of the research and its methods, to promote fully informed and voluntary participation by prospective subjects who are themselves capable of making such choices (or, if that is not possible, informed permission given by a suitable proxy) and to maximize the safety of subjects once they are enrolled in the project.

IRBs are most commonly used for studies in the fields of [medicine](#) and [psychology](#). Such studies may be *clinical trials* of new drugs or devices, they may be studies of personal or social behavior, or they may be studies of how health care is delivered and might be improved.

Responsibility

According to ICH GCP an IRB/IEC should safeguard the rights, [safety](#), and [well-being](#) of all research or trial subjects. IRB/IEC should focus on limiting harm, maximizing informed consent, and limiting pointless bureaucratic limitations of valid research.

Special attention should be paid to research or trials that may include vulnerable subjects, such as pregnant women, children, prisoners, the elderly, or persons with diminished comprehension. The primary ethical principles in human subjects review are outlined in the [Belmont Report](#), and include "*respect for persons*", "*beneficence*," and "*justice*." The IRB may only approve research for which there is a *bona fide* informed consent process for participants, for which the risks to subjects are balanced by potential benefits to society, and for which the selection of subjects presents a fair or just distribution of risks and benefits to eligible participants.

1. According to ICH GCP the IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.

2. The IRB/IEC should review a proposed [clinical trial](#) within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:

- approval/favourable opinion;
- modifications required prior to its approval/favourable opinion;
- disapproval/negative opinion; and
- termination/suspension of any prior approval/favourable opinion.

According to ICH GCP the IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

3. The IRB/IEC should obtain the following documents:

trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfill its responsibilities.

4. The IRB/IEC may request more [information](#) than is outlined in paragraph 4.8.10 be given to subjects when, in the judgment of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects. When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials. Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e., in emergency situations). The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.

5. According to ICH GCP ([good clinical practice](#)) the IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.

Member Requirement

The composition of an IRB for the FDA's requirements is set in 21 CFR 56.107.

- (a)1 The IRB must have at least five members.
- (a)2 The members must have enough experience, expertise, and diversity to make an informed decision on whether the research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place.
- (a)3 If the IRB works with studies that include vulnerable populations, the IRB should have members who are familiar with these groups. It is common for an IRB to include an advocate for prisoners when considering research that involves them.
- (b)1 The IRB should include both men and women, as long as they aren't chosen specifically for their gender.
- (b)2 The members of the IRB must not be all of the same profession.
- (c) The IRB must include at least one scientist and at least one non-scientist. These terms are not defined in the regulations.
- (d) The IRB must include at least one person who is not affiliated with the institution or in the immediate family of a person affiliated with the institution. These are commonly called "Community Members."
- (e) IRB members may not vote on their own projects.
- (f) The IRB may include consultants in their discussions to meet requirements for expertise or diversity, but only actual IRB members may vote.

In order to actually vote on a proposal, more than half of the members of the board must be present and there must be a non-scientist present. There are exceptions for expedited review, where only the chair of the committee or a designee reviews research, but these are relatively narrow.

Decision Making

Majority consent is required for none-sensitive project. Consent of all members is required for sensitive project. Project involving alive human subject is considered as sensitive project.

Members: 2008

Sean Han, M.D., Ph.D., Chairman of IRB

Zhongdong Liu, Ph.D. Director of IRB

Lutong Zhang, M.D. Director of IRB

Grace Tian, Director of IRB

Ruhong Jiang, Ph.D, Director of IRB